

NEWSLETTER

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Intellectual Property advocacy in the fields of:

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CIPROM and the Editorial Board wishing a very Happy New Year to all the Associates, Colleagues and Readers

EDITORIAL

INDIA MAKES “BOLD AND BEAUTIFUL” AMENDMENT TO THE PATENTS ACT, 1970

Section 4 of the Patents Act, 1970 which reads as follows,

“No patent shall be granted in respect of an invention relating to atomic energy falling within sub section (1) of section 20 of the Atomic Energy Act, 1962 (33 of 1962).”

has been amended as follows *“(1) The Central Government may grant patents for inventions which in its opinion are for the peaceful uses of nuclear energy and radiation:*

Provided that the inventions relating to activities specified in sub-section (5) of section 3, or which in the opinion of the Central Government, are sensitive in nature or having national security implications, shall not be patentable and such invention shall be deemed to have been made or conceived by the Central Government.

(2) Any person desirous of obtaining a patent in relation to an invention under this section shall make an application to the Controller under the Patents Act, 1970.

(3) If a question arises as to whether an invention is related to any of the activities specified in sub-section (5) of section 3 or is sensitive in nature or having national security implications, the Controller shall refer the application to the Central Government for seeking direction thereon.

(4) The Central Government may issue directions to the Controller in relation to any patent application under this Act.

(5) Any person who has reason to believe that an invention made by him is related to nuclear energy shall communicate the Central Government of its nature and description before disclosing to any third party.

(6) Any application for a patent outside India shall be governed by section 39 of the Patents Act, 1970.

(7) The Central Government shall have the power to inspect at any time any pending patent application and specification before its acceptance and if it considers that the invention does not relate to the activities referred to in sub-section (1), issue directions to the Controller to refuse the application on that ground."

It is heartening to note that India and the Indian government are opening up more and more restricted sectors for researchers and innovators. By making the above amendment, India is inviting the research community to participate in Atomic energy and other nuclear energy related inventions. This is a very welcome amendment after the recent amendments to Biodiversity Act and Rules which is acknowledged as friendly to Indian researchers.

Let us hope that India makes progress and advances to become the third largest economic powerhouse early through the expedited route and by decisive actions.

Let us hope that the reform process continues for better and stronger National future.

Link to an Editorial published in "INDIAN DRUGS"

by Dr. Gopakumar G Nair is as follows:

<https://doi.org/10.53879/id.60.10.p0005>

The Article is also reproduced below for direct access:

THE "PATENT TRANSITION STORY" - PRE & POST TRIPS

Dear Reader,

1947-1972 - 25 years of depravity

In 1968-69, the Parliamentary Select Committee, headed by Dr. Sushila Nayyar, having members such as Shri Atal Bihari Vajpayee and Shri Achutha Menon among others, called upon the nascently formed but vibrant, IDMA (Indian Drug Manufacturers' Association) and other eminent pharma experts like Shri. A.V. Mody, Dr. A.K. Hamied and others to appear before the Committee to justify the proposal for amending the Patents and Designs Act (1911) to omit granting "product" patents to drugs, foods and chemicals. The Ayyangar Committee recommendations of 1959 had led to a draft patent amendment bill from 1965, which was not passing through in Parliament (probably due to strong lobby of MNCs, then).

Around this time in 1968, a patent infringement suit filed by Farbwerke Hoechst and Bruning Corporation against Unichem Laboratories (AIR 1969 BOM 255) relating to Tolbutamide patent (IN 58716) was decided in favour of Hoechst and against Unichem. This led to the cheap generic version of Tolbutamide of Unichem, to be withdrawn leaving the branded Restinon which was more than 10 times costly. This Landmark

Judgement by the Learned Justice Vimadalal, ignited the National spirit of the then Prime Minister of India, Indira Gandhhi, who immediately pressed for passing the Patent amendment bill which was pending from 1965 to be passed in Parliament. As it happens even now, the Bill was referred to a Select Committee headed by Dr. Sushila Nayyar. Smt. Indira Gandhi wanted the Select Committee to file their report expeditiously which they did after hurriedly conducting the hearings and finalising their findings.

25 years of growth and prosperity for Indian Pharma

In 1969, the then IDMA delegation led by the then President, Mr. G.P. Nair and the General Secretary, Dr. Abraham Patani represented and presented IDMA's case for abolition of Product Patents for Pharma etc. After their presentation as over, Shri. Achutha Menon. (Later CM of Kerala) asked a question to the IDMA Team, which took them by surprise. "You say that Indian Pharma lacks research and innovation capabilities as on date (1969), when do you think they will achieve this? How long do you want exemption from Product Patents for pharma to be allowed in Patents Act?". Having taken by surprise, Mr. G.P. Nair had to reply "25 years, Sir!". Having satisfied the panel, the Select Committee recommended for abolition of Product patents for pharma, food and chemicals in the proposed patent draft. Though the Patents Act (1970) was passed, related Rules were held up thereafter. IDMA led by Shri G.P.Nair and Dr. A.Patani approached the then emerging Ranbaxy Labs CMD, Mr. Bhai Mohan Singh to take up the Presidency of IDMA so that with his help, we could get the Rules notified.

Consequently, on 20th April 1972, the Rules were notified and the Patents Act, 1970 attained legal status. These 25 years were phenomenally and historically landmark years for Indian Pharma. The IDPL (Indian Drugs & Pharmaceuticals Ltd.) came into limelight with large number of bulk drugs (Active pharmaceutical ingredients) manufactured in India, with Indian and Russian technologies. A large number of Indian entrepreneurs emerged to take advantage of the absence of "product patents" by "reverse engineering" the process technologies. A large number of Bulk drug (API) manufacturers mushroomed around Hyderabad and elsewhere as "by-products" of IDPL and HAL (Hindustan Antibiotics Ltd.). The "Hathi Committee" Report and the series of "Drug Policy" announcements by the extremely hyper-active C&F Ministry of 70s, 80s and 90s fuelled the emergence and phenomenal growth of Indian Pharma Industry post 1970. The next 25 years (post 1970) were fast getting over and the term assured by IDMA was nearing. It is then, that the WTO and TRIPs (Trade-Related Aspects of Intellectual Property Rights) came into effect resulting from the Uruguay Round of 1983 and the Dunkel Draft. India signed the TRIPs Agreement, effective 1-1-1995 (as if to materialise the 25-year promise given by IDMA in 1970). IDMA was deeply and continuously active in the Uruguay Round negotiations and Dunkel Draft finalisation to ensure that the TRIPs draft was balanced and user-friendly. We achieved this balance in most provisions of TRIPs.

Next 25 years of TRIPs compliant Patent Law and innovations

Now, in 1995, the challenge was to get a patent draft for India which is TRIPs compliant, but

maintained a sensible and stable balance between monopoly and patient's affordability-accessibility. Through the 1st, 2nd and 3rd amendments of the Indian Patents Act (in 1999, 2003, 2005) we achieved this objective by incorporating all the needful amendments as required under TRIPs without loosing the balance between rights and obligations. In next 25 years (1995-2020/2025) India has made considerable progress in innovation and pharmaceutical research outcomes. The Covid (2020-23) experience demonstrated India's resilience and potential to deliver healthcare solutions to the world, not only as "Pharmacy Capital of the world" but also as the "Vaccine Centre of global excellence". Even though, as promised by the IDMA delegation in 1968, India could not become self-reliant in New Drug (Product Patent) research and innovation, India has become a dependable global source of generic medicines, special generics and device-based delivery systems and CDMOs of excellence, India has demonstrated self-reliance in advanced globally recognised formulation and dosage form development capabilities as well as global GMP standard API (bulk drug) manufacture of dependable quality with global QC/QA standards. While India admits and accepts that India is substantially dependent on China and others for building block raw materials, with active support and contribution from the Indian Government, we are working towards self-reliance in these speciality chemical and key intermediates production, too.

In last 25 years, post WTO/TRIPs and related patent amendments, we have succeeded in TRIPs compliant patent law and related provisions.

Lately, India is entering into a large number of FTAs, partly due to global trade compulsions. Till 2025, we have succeeded in signing FTAs even with a few developed countries, without revisiting our IP related laws such as regulatory data protection. Currently, there is a need to review Indian stand vis-à-vis Article 39 (protection of test data against "unfair commercial use"). While India has already come out with the "Digital Personal Data Protection Act, 2023" (DPDP Act) followed by "DPDP" Rules in 2025, there is compulsion currently, to provide "Regulatory Data Protection" for pharmaceuticals and agrochemicals fields. India having provided for 4 years exclusivity for "New Drugs" under Drugs and Cosmetics Act 1940 (provisions in Form 44), it may not be too adverse to agree to a 3 to 4 year exclusivity of regulatory data approval, from the date of first regulatory approval anywhere in the world (in view of harmonised global regulations). While this review is in progress, let us hope that this proposal may go through without deep impact on Indian generic pharma industry.

Dr. Gopakumar G. Nair
Editor
Indian Drugs

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Rethinking Nuclear Innovation: How the SHANTI Act Reshapes India's Patent Landscape

India's nuclear regulatory framework has entered a new phase with the enactment of the Sustainable Harnessing and Advancement of Nuclear Energy for Transforming India Act, commonly known as the SHANTI Act. With presidential assent granted in December 2025, the law replaces both the Atomic Energy Act of 1962

and the Civil Liability for Nuclear Damage Act of 2010. While much attention has focused on its implications for private participation in the nuclear sector, its impact on patent law deserves equal scrutiny. At the heart of this shift lies a quiet but consequential change to Section 4 of the Patents Act. For decades, inventions relating to atomic energy were entirely excluded from patent protection. That position has now been recalibrated.

The Old Legal Position

Under the earlier regime, any invention connected to atomic energy was automatically non patentable. This flowed from Section 4 of the Patents Act read with Section 20 of the Atomic Energy Act. The exclusion was broad and unforgiving. It covered not only core nuclear technologies but also safety systems, monitoring tools, and ancillary innovations. Once the Central Government formed the opinion that an invention related to atomic energy, the patent application could not proceed.

This approach reflected the thinking of its time. Atomic energy was treated as a domain of absolute state control, shaped by national security concerns and the concentration of research within government institutions. Over time, however, this rigidity produced unintended effects. Innovators avoided filing applications in India, narrowed their claims, or excluded nuclear references altogether. Civilian technologies that merely operated in nuclear environments were treated no differently from strategic assets.

What the SHANTI Act Changes

The SHANTI Act rewrites this approach. Section 4 of the Patents Act now allows patents to be granted for inventions relating to nuclear energy, subject to the conditions laid down in Section 38 of the new legislation.

The key shift is conceptual. Patentability now turns on whether an invention is meant for peaceful use and whether it raises security or sensitivity concerns. The law no longer treats all nuclear related inventions as inherently unpatentable.

Section 38 permits patent protection for inventions that serve peaceful purposes but excludes two categories. The first covers activities reserved exclusively for the government such as enrichment and spent fuel management. The second covers inventions that the government considers sensitive or linked to national security. In both cases, the Central Government retains the authority to decide.

This structure opens space for innovation in areas such as safety systems, monitoring technologies, radiation diagnostics, control software, and industrial components that may operate in nuclear settings without posing strategic risks.

Continuing Ambiguities

While the shift is significant, the framework is far from settled. Section 38 introduces a legal fiction under which certain excluded inventions are deemed to have been conceived by the Central Government, even though they remain non patentable. The nature of the rights flowing from this deeming provision is unclear.

There is also uncertainty around remedies and review. Unlike the earlier law, the SHANTI Act does not explicitly state that government decisions under Section 38 are final. At the same time, other provisions of the Patents Act allow the government to revoke patents without appeal. How these provisions interact remains an open question.

The Act also establishes an Atomic Energy Redressal Advisory Council to hear grievances against government decisions. Whether this body will offer meaningful oversight or operate as a limited consultative forum is yet to be seen. **A Measured Shift, Not a Free Pass**

What the SHANTI Act ultimately does is replace a blanket prohibition with a controlled filter. The test is no longer whether an invention touches nuclear energy, but whether it threatens national security or falls within activities reserved for the state.

This distinction matters. Modern innovation rarely fits into neat sectoral boxes. Technologies used in nuclear facilities often overlap with those used in healthcare, clean energy, advanced manufacturing, and data systems. A legal framework that treats all such innovation as inherently sensitive stifles progress.

The new regime does not dismantle state control, but it does recalibrate it. Oversight remains strong, yet innovation is no longer excluded by default.

In that sense, the SHANTI Act marks a quiet but meaningful departure from decades of absolute restraint. It signals a willingness to distinguish

between strategic nuclear capability and civilian technological advancement, and that distinction may shape the future of innovation in India's nuclear ecosystem.

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UPL SECURES 'BEST PATENT PORTFOLIO' HONOUR AT CII INDUSTRIAL IP AWARDS 2025

UPL, a global provider of sustainable agricultural solutions, has been awarded the 'Best Patent Portfolio' in Life Science and Agriculture and recognised among the Top 30 IP-Driven Organisations (Large Enterprises) at the 11th Confederation of Indian Industry (CII) Industrial IP Awards 2025.

The CII Industrial IP Awards celebrate organisations that demonstrate excellence in intellectual property creation, protection, and commercialisation, and acknowledge their contribution to innovation-led growth and economic development. The recognition highlights UPL's continued commitment to building a robust innovation ecosystem that supports long-term value creation across the agricultural sector.

Commenting on the achievement, Dr Vishal Sodha, Global Head - IP, Product Registration and OpenAg R&D at UPL, said, "We are delighted to receive this recognition for our efforts in strengthening an IP-driven organisation. It reinforces our commitment to advancing sustainable, farmer-centric innovations that address real-world challenges and deliver value to communities and consumers. With over 3,000 granted patents worldwide and nearly 4,400 applications currently under examination, our portfolio reflects the depth and strength of UPL's research-led

innovation pipeline.”

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DELHI HIGH COURT ORDERS INTERIM HALT ON DR REDDY'S USE OF “SUN” IN SUNSCREEN BRANDING

The Delhi High Court has issued an interim order restraining Dr Reddy's Laboratories Ltd. from continuing the manufacture of sunscreen products bearing the word “SUN” on their labels. The Court held that the impugned use appeared to function as a trademark rather than as a purely descriptive reference. Dr Reddy's has been directed to maintain status quo until the next hearing.

The order was passed on 24 December 2025 by Justice Manmeet Pritam Singh Arora in a trademark infringement and passing off suit filed by Sun Pharmaceutical Industries Ltd. The dispute concerns sunscreen products marketed by Dr Reddy's under its “VENUSIA” brand.

Sun Pharma approached the Court asserting exclusive rights over the mark “SUN” and related trademarks, including “SUN PHARMA”. It submitted that these marks have been in continuous commercial use since 1978 and have been recognised as well-known trademarks by the Delhi High Court and the Trade Marks Registry.

The company also pointed out that it markets sunscreen products under the brand “SUNCROS”, which it claims derives directly from its core “SUN” mark. According to Sun Pharma, the use of “SUN” on Dr Reddy's sunscreen packaging amounts to infringement and misrepresentation of its established brand identity.

Sun Pharma informed the Court that it became

aware in June 2025 of Dr Reddy's launch of sunscreen products under the “VENUSIA” brand. While the product name differed, the packaging prominently featured the word “SUN”. Despite legal notices and subsequent correspondence, the revised labels continued to display “SUN” in a dominant manner, prompting the present action.

Dr Reddy's defended its use by contending that the word “SUN” was employed descriptively, reflecting the purpose of the product rather than indicating brand origin. It also submitted that it was willing to modify the packaging to address the concerns raised.

After reviewing the rival packaging, the Court found a *prima facie* case in favour of Sun Pharma. It observed that the placement, size, and colour of the word “SUN” made it visually dominant, diminishing the prominence of the “VENUSIA” mark. The Court noted that such presentation went beyond descriptive use and gave the impression of trademark usage.

The Court further observed that both parties operate in the same market and deal in identical goods. Given the overlapping trade channels, it held that the likelihood of consumer confusion could not be ruled out.

Accordingly, the Court restrained Dr Reddy's from further use of the impugned label and directed maintenance of the existing position until further orders.

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MADRAS HIGH COURT DIRECTS PATENT OFFICE TO ALLOW DEMONSTRATION OF INVENTION BEFORE FINAL REJECTION

The Madras High Court has directed the Patent Office to provide an inventor with an opportunity to demonstrate his invention before arriving at a final decision on the grant of a patent, underscoring the importance of procedural fairness in patent examination.

In *Kannan Gopalakrishnan v. Controller of Patents*, the petitioner challenged the rejection of his patent application titled “Solar Supplemental Power Source”. The application had been refused under Section 3(a) of the Patents Act, 1970, on the ground that the claimed invention was contrary to established natural laws. A subsequent review petition filed by the applicant was also rejected without granting a personal hearing.

The petitioner contended that the invention involved a functional mechanical system capable of generating electricity through a combination of gravitational and buoyant forces. He submitted that a working prototype was available and that the rejection was premature, having been made without affording an opportunity to demonstrate the invention’s operation.

The Court noted that while the Patent Office had relied on Section 3(a) to reject the application, the petitioner had specifically sought a chance to substantiate the technical feasibility of the invention through a demonstration. Observing that patent rights constitute valuable statutory rights, the Court held that such rights should not be denied without affording adequate procedural safeguards.

Although the Court acknowledged that the review

authority had acted within the framework of the statute, it exercised its discretionary jurisdiction under Article 226 of the Constitution to ensure fairness. The Court directed the petitioner to present the prototype before the Assistant Controller of Patents within four weeks. The Patent Office was further directed to permit the demonstration and pass a reasoned order within four months thereafter.

The decision reflects the Court’s emphasis on balancing statutory compliance with fairness in patent administration, particularly where an inventor seeks an opportunity to substantiate the technical merits of an invention before final rejection.

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DELHI HIGH COURT CLARIFIES “PROOF OF RIGHT” REQUIREMENTS IN PATENT APPLICATIONS

The Delhi High Court, in *Nippon Steel Corporation v. Controller of Patents* (C.A.(COMM.IPD-PAT) 10/2025, decided on 24 December 2025), set aside the refusal of a patent application and clarified the scope of “proof of right” under Sections 6 and 7 of the Patents Act, 1970.

The appeal arose from the rejection of a patent application relating to a “High-Strength Steel Sheet and Manufacturing Method” on the ground that the applicant had failed to establish valid proof of right in respect of one of the inventors who had passed away prior to grant. The Controller had held that the employment agreement and supporting declaration submitted by the applicant were insufficient, and that a specific assignment or documentation from the

legal representative of the deceased inventor was mandatory.

The Court examined whether an employment agreement, read with internal corporate regulations governing intellectual property ownership, could constitute valid proof of right under Section 7(2) of the Act. It held that the statutory requirement does not mandate a formal assignment deed in every case, particularly where the invention arises in the course of employment and the contractual framework clearly vests intellectual property rights in the employer.

The Court noted that Section 68 of the Act applies to assignments of granted patents and not to the assignment of the right to apply for a patent. It further observed that the Controller had taken an unduly technical view by rejecting the application despite the existence of a duly executed employment agreement and consistent past practice of accepting similar documentation in earlier patents granted to the same applicant.

Emphasising that procedural law should facilitate rather than obstruct substantive justice, the Court held that the employer-employee agreement constituted valid proof of right under Section 7(2). The rejection order was therefore set aside, and the Controller was directed to proceed with the examination and grant of the patent in accordance with law.

The decision reinforces a pragmatic interpretation of “proof of right” and affirms that employment agreements can constitute valid evidence of entitlement to apply for a patent, particularly in cases involving corporate inventorship and established internal IP policies.

